

Review Article

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Suicide and Antidepressants: What Current Evidence Indicates

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ABSTRACT

The documented efficacy and long-term benefit of antidepressants in patients with recurrent forms of severe anxiety or depressive disorders support their use in those individuals with these disorders, who experience suicidal thoughts or behavior. In general, it is assumed that antidepressants are beneficial for all symptoms of depression, including suicidality. However, some evidence suggests that Selective Serotonin Reuptake Inhibitors [SSRIs] may cause worsening of suicidal ideas in vulnerable patients. Systematic reviews and pooled analysis of experimental, observational, and epidemiological studies have investigated the use of SSRIs and their association with suicidality. Taking account of the methodological limitations of these studies, the current evidence fails to provide a clear relationship between their use and risk of suicidality in adults. However, in children and adolescents, there appears to be a bit of increased risk of suicidal ideations and attempts, but not of completed suicides. This risk can be anticipated and managed clinically. Clinicians are, therefore, advised to maintain a close follow-up during the initial treatment periods and remain vigilant of this risk. This advisory, however, should not deter clinicians from the use of effective dosages of antidepressants for a sufficient period of time, in every age group of patients, when clinically needed, and if found suitable otherwise.

Key Words: *Antidepressant; Depression; Risk of SSRIs to children and adolescents; Selective Serotonin Reuptake Inhibitors; Suicidality; Suicide*

Introduction

Debate persists on whether some antidepressant drugs (ADs), in particular

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the Selective Serotonin Reuptake Inhibitors (SSRIs), cause the emergence or worsening of suicidal ideas in vulnerable patients. Across the globe, ADs, especially SSRIs, are among the most commonly prescribed medications (Stafford, 2001^[26]). Large amounts of prescriptions are written because of the perception and knowledge that they are largely safe and effective across a wide variety of common disorders, namely depression and anxiety disorders. Concerns related to safety were initially raised in the early 1990s, with reports that described a possible association with suicidality (Teicher *et al.*, 1990^[28]), and from time to time later (Healy, 2004^[11]). However, inferences regarding the plausibility and strength of the association between suicidality and the use of SSRIs have been conflicting and inconclusive (Khan *et al.*, 2000^[15], 2003^[16]; Simon *et al.*, 2006^[24]).

In recent times, in order to get more information on the issue, many different study designs, including randomized clinical trials, observational studies, and ecological time trend analyses have been performed. Each of these research designs, with their unique strengths and limitations, have contributed by generating information that may be used to guide clinical practice patterns.

We summarize the current evidence, to generate evidence-based suggestions, for day-to-day clinical work. We have adopted a descriptive view of data presentation in this article to elucidate the relevant findings and produce useful clinical insights into this highly conflicting issue.

Ecological Studies

Ecological analyses have investigated whether the increasing use of SSRIs is associated with benefits in terms of decreasing rates of suicide. Evidence that antidepressants and other interventions offered by mental health professionals yield the expected reductions in risk of suicides or attempts is mixed (Singh, 2004^[25]). Correlative pharmacoepidemiological studies have compared suicide rates by regions or years with the concurrent rates of prescriptions for antidepressants (Baldessarini and Tonda, 2007^[3]). Several studies in US and Nordic countries (Scandinavian countries of northern Europe) have shown that emergence of modern, less toxic antidepressants, over the past decade, which dominate the current clinical practice, was associated with a generally moderate decrease in the overall suicide rates, varying in sex and age groups. Isacson, 2000^[12], analyzed national statistics on suicide, alcohol consumption, unemployment, and the use of ADs, for the period 1978 - 1996, in Sweden, Denmark, Norway, and Finland. The study reported a reduction in suicide rates by 19%, in parallel with the increased use of ADs in these countries. However, in women under the age of 30 and over 75 years, the suicide rates remained unchanged, despite an increased consumption of ADs. Overall, Isacson^[12] concluded that the increased use of ADs appeared to be one of the contributing factors to the decrease in suicide rate.

However, evidence also suggests that similar trends of reduction in suicide rates were observed at least a decade ago, before the introduction of the first SSRI, Fluoxetine, in the US market and in some Nordic nations (Reseland *et al.*, 2006^[21]). This suggests that many other factors were also operational in the reduction of suicide rates in these nations. Baldessarini and Tonda, 2007,^[3] reported that only nine of the 29 ecological studies found significant inverse correlations of the increased use of modern antidepressants with diminishing national, regional or temporal trends in suicide rates; another 14 studies found correlations in some sex or age subgroups, who were inconsistent across the studies; and six found no significant relationships. Same analysis of the data from 78 reporting countries indicated that about half (54%) experienced a decrease in annual suicide rates between the 1950s (when antidepressants were not available) and early 2000s (a decade after the introduction of modern antidepressants); and a similar proportion (46%) reported an increase. Moreover, both types of changes have been reported from similar world regions, including a decrease and increase in Western and Eastern Europe, Latin America, and Asia. These outcomes suggest random or at least highly complex phenomena, likely to reflect the impact of many contributing factors.

Studies looking for suicide rates in a specific age group have shown different results. Pharmacoepidemiological data from the US suggest that paralleling the widespread use of SSRIs, the suicide rates among those aged 15 - 19 years fell from 11 / 100,000 in 1990 to 7.3 / 100,000 in 2003; and synchronous with the US FDA black box warning on antidepressants and the likely reduction in antidepressant usage in 2004, the suicide rates climbed to 18 for those younger than 20 years – from 1,737 to 1,985 deaths (Hamilton *et al.*, 2005^[9]).

Results of such ecological studies are influenced by a variety of factors, like improvement in public health, changes in legal, cultural or social prohibitions against suicide, improvement in identifying and reporting suicides, and increased access of more people to modern antidepressants (Barbui *et al.*, 2007^[4]). Tonda *et al.*, 2006^[30], found a strong correlation between state suicide rates and economic and demographic measures, likely to be associated with access to clinical care in general, including population density, clinician / 100,000 population, per capita income, access to medical insurance, and public support of mental health services. Although such studies may suggest hypothesis to be tested by more sophisticated measures, they cannot prove a direct, casual relationship between antidepressant treatment and reduced risk of suicide at the level of individuals.

Barring a few studies, the ecological studies in general, suggest the possible benefits of ADs exposure in the needy population. It is also important to emphasize that all ecological studies suffer from a fundamental inability to relate antidepressant exposure to suicidal behavior, at the level of the individual.

Case Control and Cohort Studies / Observational Studies

Observational evidence is present from large cohorts of depressed patients from general practice or the health maintenance organizations' data source and from the relatively large case control comparisons of subgroups, varying in exposure to antidepressants. Olfson *et al.*, 2006,^[19] in a matched case-control study, estimated the relative risk of suicide attempts and suicidal deaths in severely depressed children and adults treated with ADs versus those not treated with AD drugs. In these high-risk patients, AD drug treatment did not seem to be related to suicide attempts and deaths in adults, but it might be related in children and adolescents. Juurlink *et al.*, 2006,^[14] studied population-based coroner's records and found that during the first month of therapy, SSRI use was associated with a nearly five-fold higher risk of completed suicide than other ADs. However, the absolute risk was low in comparison to untreated patients. This suggests that an idiosyncratic response to SSRIs may provoke suicide in a vulnerable subgroup of patients.

Simon *et al.*, 2006,^[24] assessed the suicide risk during antidepressant treatment by computerized health plan records and identified around 65,000 individuals with 82,000 episodes of AD treatment. The study did not suggest significant increased risk of suicide or serious suicide attempts after starting treatment with newer AD drugs.

Martinez *et al.*, 2005,^[18] conducted a nested case-control study based on information extracted from the General Practice Research Database, and analyzed the risk of non-fatal self-harm and suicide in patients with a new diagnosis of depression, who were prescribed SSRIs or tricyclics. The cohort included 146,095 patients. Patients taking SSRIs were not at an increased risk of suicide or non-fatal self-harm. However, in patients aged 18 years or less, weak evidence indicated a higher risk of non-fatal self-harm.

Isacsson *et al.*, 2005,^[13] adopting a different approach, analyzed detection of different ADs in the forensic toxicological screening of 14,857 suicides compared to 26,422 cases of death by natural or accidental causes in Sweden from 1992 to 2000. This analysis did not support the increased risk of suicidality following AD treatment in Sweden over a period of nine years.

Interpretation of finding from these studies is significantly compromised by the risk of 'confounding by morbidity or by indication.' That is, medical treatment in general is more likely to be sought and given to more severely ill patients at a higher risk of suicide, and lesser toxic drugs are likely to be selected for patients at an increased risk for suicide. The non-randomized, clinically selected treatment in such studies can severely distort the observed associations between a greater suicide risk and use of particular treatments. Although many studies statistically adjusted for this possible confounder, the possibility that

other known and unknown variables might have acted in unpredictable ways, cannot be ruled out. However, these studies do not provide information about any risk of suicidality with ADs in adults with depression. The need for more supervision in children and adolescents regarding suicidality subsequent to exposure of ADs is advised.

Randomized Controlled Trials

Randomized Controlled Trials (RCTs) should be the best source of data on the effects of antidepressant treatment on suicidal risks, and hundreds of RCTs support the licensing and clinical utility of ADs in a variety of psychiatric disorders. Several systemic reviews and pooled analysis of RCTs have evaluated this issue.

Fergusson *et al.*, 2005,^[7] reviewed all published 702 RCTs, which included 87,650 patients, comparing SSRIs with placebo or other antidepressants. Almost a two-fold increase in the odds of suicidal attempts, but not in completed suicides, in SSRI users, was found compared to placebo or other therapeutic interventions. However, no difference was observed when a comparison between SSRIs and TCAs was made. Some serious limitations to this review were present, most important being lack of any information on adverse events for 58% of the patients eligible for analysis. Many other meta-analyses had also found an overall greater risk with antidepressants (Tollefson *et al.*, 1994^[29], Khan *et al.*, 2000^[16], 2003^[15]; Storosum *et al.*, 2001^[27]).

In contrast, Gunnell *et al.*, 2005^[8], reviewed both published and unpublished randomized trials submitted by pharmaceutical companies to the safety review of the Medicine and Healthcare products Regulatory Agency (MHRA), in depression and other clinical conditions. The outcome measures were completed suicide, non-fatal self-harm, and suicidal thoughts. This study reported no evidence of an increased risk of completed suicide, weak evidence of increased risk of self-harm, and inconclusive evidence of an increased risk of suicidal thoughts, with estimates compatible with modest protective or adverse effects.

The largest of these analyses was recently organized by the US Food and Drug Administration (FDA) to review all available data from 386 controlled trials of modern antidepressants involving 112,875 patient-subjects with major depressive or other disorders (Laughren, 2006^[17]). This found no overall difference in the risk of 'Suicidality' (mainly suicidal ideation). However, on performing a secondary analysis by age-stratified measures, they suggested a differential risk of antidepressant-induced suicidality across the age spectrum, with a greater risk at the younger end of the spectrum, and a declining risk with aging, and perhaps even a protective effect in the elderly.

Concerns over safety of the use of SSRIs in children and adolescents have become paramount following the extensive review by British and American regulatory agencies. Hammad *et al.*, 2006^[10], in a review of both published and unpublished clinical trials using SSRIs in children and adolescents with depression and other indications (N > 4,400 subjects, across 26 controlled trials, 16 of them for depression), revealed an increased risk of new onset suicidal ideation between SSRI- and placebo-treated individuals (occurring at the respective rates of 4 and 2%, for a risk ratio of 1.95). However, all reported events refer to suicidal ideation rather than suicidal acts or completed suicide.

Trials of ADs in adults have found a substantially larger reduction in the average rating of suicidal ideations with AD than placebo (Pedersen, 2005^[20]; Acharya *et al.*, 2006^[11]). However, these findings were based on *post hoc* analysis of individual items on standard depression symptom rating scales (HAM-D, MADRS), which could shift coincidentally with overall clinical improvement. Studies with ADs that explicitly considered suicidal ideation and behavior as outcome measures remain to be carried out.

Randomized Controlled Trials have limitations that can lead to uncertainties and artefacts. These include potentially unreliable, incidental, passive reporting of suicidal thoughts or behaviors in most RCTs, based on conditions not designated explicitly to detect suicidal events. The short-term bases of most clinical trials for acute depression also do not provide an adequate basis of evaluating the effect of ADs on rare suicidal behavior. Much of the reported events involve suicidal ideation of highly uncertain clinical significance and quantitatively very limited relationship to actual life-threatening behavior. In the placebo arm, the dropout rates are significantly higher owing to perceived lack of treatment efficacy, which can limit observable suicidal risk in the placebo arm, leading to an interpretation that active treatment is 'riskier' than placebo. Although procedure of pooling data from a large number of trials increases the overall sample, the absolute number of patients attempting or committing suicide remained low. This leaves a possibility that even reporting or not reporting a few cases could have completely changed the overall outcome (Cipriani *et al.*, 2005^[5]). Reduction in risk might not be observed as readily over short time periods, or in studies in which suicidality was used as an exclusion criterion.

The preceding findings have been widely debated and have created a huge attention of the lay media and public to this issue. Responding to this, the US FDA recommended revision of drug manufacturers' information bulletins to include a highlighted 'Black Box' warning of the risk for possible emergence of suicidality.

Therefore, data pooled from relatively brief, randomized controlled trials in acute major depression in the young and elderly adults fail to suggest the risk of suicidality. In children and adolescents, few vulnerable cases may experience

increase in suicidal ideations at the start of treatment. Hence, a clinician should routinely assess the risk and benefit ratio of an individual case, before prescribing ADs for them.

Discussion

Possible reasons why ADs might increase the risk of suicide are discussed herewith.

Antidepressant therapy typically involves a substantial delay before clinically obvious improvements occur. During initial, partial recovery, it is possible that suicidal impulses as well as the energy to act on them may increase. Patients should be forewarned of this likely delay in treatment effects, should be given encouragement and monitored especially closely in the initial days and weeks of treatment. If full response to treatment is not observed, adjustments in medication dosage, or a change to a different antidepressant, may be necessary.

Heterogeneity in the psychopharmacological effects of SSRIs suggests that some patients might experience a worsening of mood with SSRI treatment. Undiagnosed bipolar disorder, especially Type II, may be present in patients presenting with depression. Recent studies suggest that antidepressants might worsen the mood in patients with undiagnosed bipolar disorder (Baldessarini *et al.*, 2006^[21]) and may cause agitation and impulsivity, and exacerbate psychosis, resulting in an increased risk of suicide. If such symptoms emerge during the course of treatment of depression, the ADs should be stopped and appropriate treatment for Bipolar Disorder started.

Pharmacotherapy of mild depression is under greater scrutiny and should be decided on a case-to-case basis. Higher risk in children and adolescents should encourage clinicians to be more cautious in their management: they should resort to pharmacotherapy only after considering the risk / benefit ratio in each patient. Guidelines from the US FDA and American Academy of Child and Adolescent Psychiatry (AACAP) call for intensive monitoring during the early phase of treatment: as often as weekly for the first four weeks, fortnightly for the next month, and monthly thereafter (FDA, 2007^[6]; Rey and Martin, 2006^[22]). However, concerns have been raised that such guidelines may deter some clinicians from using ADs if they are unable to provide such monitoring, especially in underserved areas, and thus deserving patients may be denied the right treatment (Scahill *et al.*, 2007^[23]).

Conclusions [See also Figure 1: Flowchart of Paper]

Understanding the effects of SSRI antidepressants on suicide is important for government regulators as well as for doctors, patients, and the family and

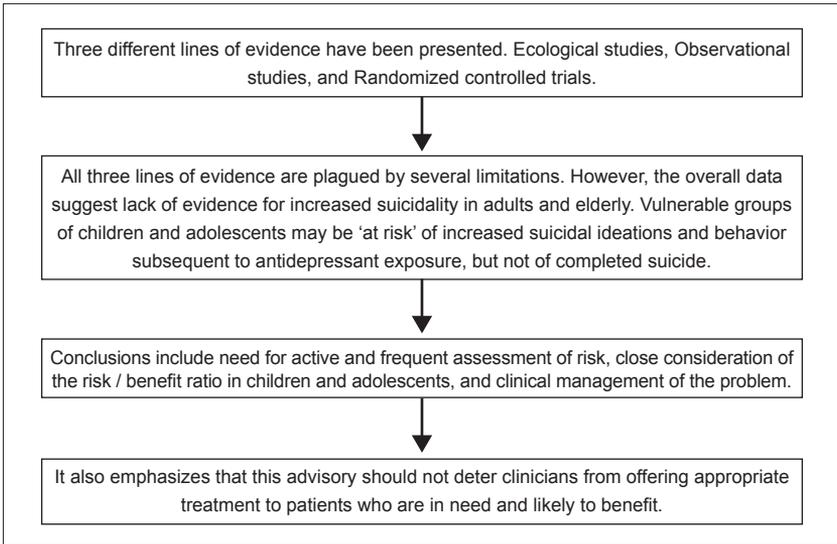


Figure 1: Flowchart of the paper

friends of those suffering from illnesses requiring AD treatment. Taking into account available evidence, and limitations of the evidence available, following insights for clinical practice can be highlighted:

- Available evidence is in favor of effectiveness of these agents in many clinical conditions; so clinicians should prescribe effective dosage of medications to those in need.
- The current evidence fails to conclusively establish a relationship between increased suicidal ideation and behavior after use of AD medications. At best it suggests some increased risk for children and adolescents.
- Clinicians should be aware of the fact that both TCAs and SSRIs may induce or cause worsening of suicidal ideations; hence, there is a need for early follow-up and encouraging support and supervision of patients, especially in the early phase of treatment.
- However, this adverse effect can usually be anticipated and identified clinically, and treatment can be appropriately modified in time, such as, offering greater psychological support, removing ADs, adding anxiolytics, antipsychotics or mood-stabilizing agents, as may be deemed necessary.

Take home message

1. Caution is advisable during prescription of antidepressants to patients, especially in children and adolescents, as it may precipitate suicidal ideation in some vulnerable patients.

2. However, this can be readily identified and managed clinically, and it should not deter clinicians from providing effective pharmacological treatment to those in need.

Conflict of interest

None declared.

Declaration

This is our original unpublished work, not under consideration for publication elsewhere.

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Questions that this Paper Raises

1. What are the reasons for the age-wise distribution of change in suicidality subsequent to exposure to antidepressants, in patients with depression?
2. Is there a differential risk of antidepressants for increased suicidality in children and adolescents? What is their relative risk?
3. What are the determinants of increased suicidal risk in these patients?
4. Do ADs reduce suicidal ideation, attempts, or completed suicides in patients?

About the Author



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